Data Evaluation Record on the Acute Oral Toxicity of Transfluthrin (NAK 4455 technical) to Bobwhite Quail (*Colinus virginianus*)

PMRA Submission Number {.....} EPA MRID Number 49617836

Data Requirement:	PMRA Data Code	{.....}
	EPA DP Barcode	436376
	OECD Data Point	{.....}
	EPA MRID	49617836
	EPA Guideline	850.2100 (OCSPP)

Test material: Transfluthrin **Purity:** 94.5%
Common name: NAK 4455 technical
Chemical name: IUPAC ,3,5,6-tetrafluorobenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; or 2,3,5,6-tetrafluorobenzyl (1*R*)-*trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
CAS name: (2,3,5,6-tetrafluorophenyl)methyl (1*R*,3*S*)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate
CAS No.: 118712-89-3
Synonyms: None

Primary Reviewer: Rebecca L. Bryan **Signature:** Rebecca L. Bryan
Staff Scientist, CDM/CSS-Dynamac JV **Date:** 1/25/2017

Secondary Reviewer: Elizabeth Krupka **Signature:**
Environmental Scientist, CDM/CSS-Dynamac JV **Date:** 2/8/2017

Primary Reviewer: Frank T. Farruggia, Ph.D. **Date:** 9/11/2017 2017.09.11 14:26:42 -04'00'
{EPA/OECD/PMRA}

Secondary Reviewer(s): {.....} **Date:** {.....}
{EPA/OECD/PMRA}

Reference/Submission No.: {.....}

Company Code	{.....}	[For PMRA]
Active Code	{.....}	[For PMRA]
Use Site Category	{.....}	[For PMRA]
EPA PC Code	129140	

Date Evaluation Completed: 11-09-2017

CITATION: Grau, R. 1987. Acute Oral LD50 of NAK 4455 to Bobwhite Quail. Unpublished study performed by Bayer AG, Crop Protection-Research, Chemical Product Development and Environmental Biology, Institute for Environmental Biology, Leverkusen, Germany. Laboratory Study No. E2920022-7. Study sponsored by Bayer CropScience, Monheim am Rhein, Germany. Study initiated March 17, 1987 and completed November 16, 1987.

DISCLAIMER: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute oral toxicity of a pesticide to avian species. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study. This Data Evaluation Record may

have been altered by the Environmental Fate and Effects Division subsequent to signing by CDM/CSS-Dynamac JV personnel.

EXECUTIVE SUMMARY:

The acute oral toxicity of NAK 4455 technical (Transfluthrin) to 17-week old Bobwhite quail (*Colinus virginianus*) was assessed over 14 days. NAK 4455 technical (Transfluthrin) was administered to the birds using gelatin capsules at the limit dose of 2000 mg ai/kg with a negative control group. After 14 days, no mortalities or sublethal effects were observed in the control or 2000 mg ai/kg treatment groups. No treatment-related effects on body weights or feed consumption were observed. The acute oral LD_{50} was estimated as >2000 mg ai/kg, the limit test concentration. The NOAEL was ≥2000 mg ai/kg based on lack of treatment-related effects.

According to the U.S. EPA classification system, NAK 4455 technical (Transfluthrin) would be classified as **practically nontoxic** to Bobwhite quail (*Colinus virginianus*) on an acute oral basis.

This study is scientifically sound and is classified as acceptable.

Results Synopsis

Test Organism Size/Age (Weight range): Adult, 17 weeks old (148 to 220 g)

LD_{50}: >2000 mg ai/kg 95% C.I.: N/A
Slope: N/A 95% C.I.: N/A

Endpoint(s) affected: None

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was based on procedures outlined in U.S. EPA Pesticide Assessment Guidelines, §71-1 (1982) and OCSPP Guideline 850.2100. The deviation from U.S. EPA OCSPP 850.2100 guidance included:

1. Photoperiod hours not reported. Temperature and relative humidity during testing were not specified.
2. The confirmation of the test dose was not assessed.

These deviations do not affect the scientific soundness of this study.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. This study was conducted in compliance with U.S. Environmental Protection Agency GLP standards (40 CFR Parts 160 and 792) and OECD C (81) 30 (Final).

A. MATERIALS:

1. Test material:	NAK 4455 technical (Transfluthrin)
Description:	Dark brown liquid (1.33 g/mL density)
Lot No./Batch No.:	130187
Purity:	94.5%
Stability of compound under test conditions:	Not assessed
Storage conditions of test chemicals:	Not reported

Physicochemical properties of NAK 4455 technical (Transfluthrin).

Parameter	Values	Comments
Water solubility at 20°C	Not reported	
Vapor pressure	Not reported	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

(OECD recommends water solubility, stability in water and light, pKa, Pow, and vapor pressure of test compound)

2. Test Organism:

Species (common and scientific names): Bobwhite quail (*Colinus virginianus*)
Age at study initiation: Adult, 17 weeks old
Weight at study initiation (range): 148 to 220 g
Source: In-house laboratory hatch (originally from Cumberland, Virginia, USA)

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding study: No range-finding study was reported.

b. Definitive study:

Table 1: Experimental Parameters

Parameter	Details	Remarks *Criteria*
Acclimation Period:	14 days	*The recommended acclimation period is a minimum of 15 days. OECD recommends a minimum of 7 days.*
Conditions: (same as test or not)	Birds were housed in group cages (70 x 70 x 70 cm) with 5 animals each. Temperature and relative humidity conditions were the same as test.	
Feeding:	Kükenstarterfutter KST 60 diet with head lettuce, and drinking water were available *ad libitum*.	
Health: (any mortality observed)	Birds appeared healthy at the beginning of acclimation. An antibiotic (zinc bacitracin) and a coccidiostatic substance (Amprolium-Ethopabat) were provided prophylactically with the diet.	
Pen size and construction materials:	20 x 17 x 13 cm (construction materials not reported).	Birds were housed individually during testing. *Pen size and construction should conform to good husbandry practices and should not create crowding stress.* *OECD recommends that pens be suitable for the captive rearing of that species.*
Test duration:	14 days	*Recommended test duration is one day for dosing and at least 14 days observation.*
Dose preparation [Indicate method of confirmation of dose]	The test substance was placed in gelatin capsules and dosed neat.	Confirmation of dosing was not assessed.
Mode of dose administration:	Gelatin capsule	*Gavage or gelatin capsule is recommended*
Dose levels Nominal:	0 (control) and 2000 mg ai/kg	

Parameter	Details	Remarks
		Criteria
Measured:	Not determined	*Dose levels should be a minimum of 5 treatment levels unless LD_{50} is demonstrated to be greater than 2000 mg ae/kg*
Solvent/vehicle, if used Type: Amount/bw:	 N/A N/A	*The test material should be administered without a vehicle if possible. Maximum vehicle should not exceed 0.1 to 1.0% of body weight.*
Number of birds per group/treatment Negative control: Solvent/vehicle control: Treated:	 10 (5 per sex) N/A 10 (5 per sex)	*Recommended number of birds in a treatment group is 10 and 10 birds for each control and vehicle group.*
No. of feed withholding days before dosing	15 hours	During the test, the Batteriefutter LAB 50 diet was provided. *Food should be withheld for at least 15 hours prior to dosing.*
Test conditions Temperature: Relative humidity: Photoperiod:	 18-20°C (prior to test) 20-40% (prior to test) Daylight	Photoperiod hours not reported. Temperature and relative humidity during testing not specified. *The recommended photoperiod is 10 hours of light and 14 hours of dark.*
Reference chemical, if used Name: Concentrations tested:	 None tested	

2. Observations:

Table 2: Observations

Criteria	Details	Remarks *Criteria*
Parameters measured (mortality/individual body weight at test initiation and termination/ mean feed consumption/ others)	- Mortality - Clinical signs of toxicity - Body weight - Food consumption	*Body weight should be measured at test initiation, on day 14 and at the end of the test if the test is extended beyond 14 days. Mortality should not be more than 10% in controls.* *Feed consumption should be measured as average daily food consumption.*
Indicate if the test material was regurgitated	No regurgitation was reported.	*Regurgitation is an indication that the dose was rejected. If this problem persists, the test should be repeated.*
Groups on which necropsies were performed	Necropsies were conducted on all surviving birds.	*Gross necropsies should be performed with inspections of the GI tract, liver, kidneys, heart, and spleen.*
Observation intervals	Birds were observed for mortality and clinical signs of toxicity continuously the first hour after dosing and then hourly on Day 0, and once daily thereafter (except on weekends). Individual body weights were recorded on Days 0, 7, and 14. Food consumption was recorded for Days 7-14.	
Were raw data included?	Yes	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

No mortalities were observed in the control or 2000 mg ai/kg group. The acute oral LD_{50} was estimated as >2000 mg ai/kg.

Table 3: Effect of NAK 4455 Technical (Transfluthrin) on Mortality of the Bobwhite Quail.

Treatment (mg ai/kg)	No. of Birds	Cumulative Mortality				
		Day 0	Day 1	Day 7	Day 10	Day 14
Control	10	0	0	0	0	0
2000	10	0	0	0	0	0
NOAEL	≥ 2000 mg ai/kg					
LD_{50} (with 95% C.I.)	>2000 mg ai/kg					

B. SUBLETHAL TOXICITY ENDPOINTS:

All control and 2000 mg ai/kg birds were normal in appearance and behavior throughout the study. No treatment-related changes in organs of the 2000 mg ai/kg birds were observed during the gross pathological examination.

There were no treatment-related effects for body weights or feed consumption at any interval for 2000 mg ai/kg group birds compared to the control.

Table 4: Sublethal Effects of NAK 4455 Technical (Transfluthrin) on the Bobwhite Quail. [a]

Mean Body Weight, g ± SD			
Treatment, (mg ai/kg)	Males and Females		
	Day 0	Day 7	Day 14
Control	180 ± 12	183 ± 12	186 ± 11
2000	176 ± 19	178 ± 21	186 ± 22
NOAEL	≥ 2000 mg ai/kg		
EC_{50}	Not reported		
Mean Feed Consumption, g/bird/day			
Treatment, (mg ai/kg)	**Days 7-14**		
Control	25.3		
2000	19.6		
NOAEL	≥ 2000 mg ai/kg		
EC_{50}	Not reported		

a Data obtained from Table 3 on page 14 of the study report.

C. REPORTED STATISTICS:

The LC_{50} value was determined to be >2000 mg ai/kg, the only treatment group tested.

LD_{50}: >2000 mg ai/kg 95% C.I.: N/A
Slope: N/A 95% C.I.: N/A

Endpoint(s) affected: None

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method:
Statistical Method: The reviewer entered the mortality, body weight change, and regurgitation data into the database/program CETIS version 1.8.7.12, with backend settings implemented by EFED on 10/20/15. The nominal test concentrations were used. The LD_{50} was empirically determined by the reviewer due to a complete lack of mortality in this study.

LD_{50}: >2000 mg ai/kg 95% C.I.: N/A
Slope: N/A 95% C.I.: N/A

Endpoint(s) affected: None

E. STUDY DEFICIENCIES:

There were no deficiencies from OCSPP 850.2100 (2012) guidance that would affect the scientific soundness or acceptability of this study.

F. REVIEWER'S COMMENTS:

The reviewer agrees with the Study Author's results. Due to a lack of mortality, both the reviewer and the study author estimated the LD_{50} to be >2000 mg ai/kg.

The in-life phase of the definitive study was conducted March 17-31, 1987.

G. CONCLUSIONS:

This study is scientifically sound and is classified as acceptable. After 14 days, no mortalities or sublethal effects were observed in the control or 2000 mg ai/kg treatment groups. No apparent treatment-related effects on body weights or feed consumption were observed. The acute oral LD_{50} was estimated as >2000 mg ai/kg, the limit test concentration.

LD_{50}: >2000 mg ai/kg 95% C.I.: N/A
Slope: N/A 95% C.I.: N/A
Endpoint(s) affected: None

III. REFERENCES: None